

REMARKS

Reconsideration and withdrawal of the rejections are respectfully requested in view of the amendments and remarks herein.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 24-28, 31, 32, 35-46 and 54 are under consideration in this application. Claim 24 has been amended; claim 54 has been added. Support for the amendment can be found throughout the specification. Support for the hybridization conditions recited in claim 54 can be found in Example 4 on page 33 of the specification.

No new matter is added by this amendment.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited by the Examiner, and that these claims were in full compliance with the requirements of 35 U.S.C. §112. The amendments of and additions to the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply for clarification and to round out the scope of protection to which Applicants are entitled. Furthermore, it is expressly stated that these amendments are not narrowing amendments.

II. THE REJECTIONS UNDER 35 U.S.C. §112, 1ST PARAGRAPH, ARE OVERCOME

Claims 24-29, 31, 32 and 35-46 were rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking adequate written description and enablement. The rejections are traversed.

The Office Action alleges on page 3 that “[a] description of the function of the enzyme does not satisfy the written description requirement for claims drawn to sequences exhibiting less than 100% sequence identity when compared to a specific SEQ ID NO.” The Examiner’s attention is drawn to Example 14 of the USPTO’s “Synopsis of Application of Written Description Guidelines”. Example 14 presents a fact pattern that is analogous with that of the instant application. The claim in Example 14 recites the structure of the claimed protein, in the form of a SEQ ID NO and variants with a particular percent identity to the recited sequence, and function in the form of identifying the reaction that the protein catalyzes (*i.e.* its enzymatic activity). Claim 24 of the instant application recites (1) structure of the claimed protein in the form of a SEQ ID NO, and variants having over 90% identity with the nucleic acid molecule encoding the claimed protein and (2) function of the claimed protein in the form of its isoamylase activity.

The Office Action goes on to allege that “Applicant are not entitled to a genus when they only disclose one species.” Firstly, it should be noted that Applicants have disclosed two wheat isoamylases (SEQ ID NO:3 and SEQ ID NO:7) and the nucleic acid sequences that encode them. Secondly, as discussed in Example 14, even if the claimed SEQ ID NO is the only species disclosed, it is representative of the genus because all members of the genus have the claimed level of identity with, and function of, the protein described by the reference sequence. In the case of the current application, however, not just one, but two members of the genus are disclosed, providing even more evidence than is necessary, according to Example 14 of the Written Description Guidelines, to meet the written description requirement of 35 U.S.C. §112, first paragraph. The Examiner is also respectfully invited to review recently issued U.S. Patent Nos. 6,623,948, 6,617,143, 6,590,141 and 6,521,433, all of which contain claims with percent identity language applied to the entire claimed molecule, and not a particular domain.

Applicants have clearly provided relevant, identifying structural characteristics in the form of the nucleotide and amino acid sequences of two wheat isoamylases, and their enzymatic function is taught in the specification. There are reasonable limits regarding what the claimed nucleic acid molecules can comprise. The fact that they are not necessarily required to comprise the exact disclosed sequence does not render them inadequately described.

With respect to enablement, claim 24 has been amended to remove the hybridization language. A nucleic acid molecule that hybridizes to the nucleic acid molecule of claim 24 is claimed in new claim 54, which recites specific hybridization conditions. These conditions are taught in Example 4, and were used to isolate the nucleic acid molecule of SEQ ID NO:6, encoding SEQ ID NO:7, which is a species of the genus claimed in claim 24. Further, claim 24 has been limited to nucleic acid molecules isolated from wheat, thereby addressing the “multitude of plants” concern expressed in the Office Action.

Applicants maintain that limiting the claims to only the nucleotide sequence of SEQ ID NO:2 would unfairly narrow the scope of the invention. Applicants further assert that the requirements of the first paragraph of Section 112 have been met: two members of the genus claimed in claim 24 have been identified, using methods taught in Examples 1 and 4 of the application, and adequate structural and functional characteristics are recited in the claims. Consequently, reconsideration and withdrawal of the rejections under 35 U.S.C. §112, first paragraph, are requested.

III. THE REJECTION UNDER 35 U.S.C. §102 IS OVERCOME

Claims 24-28, 31, 32, 35-42 and 45 were rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Kossman *et al.* The rejection is traversed.

Kossman *et al.* relates to a soluble starch synthase and a starch granule-bound starch synthase from potato. Applicants reiterate that these are completely different enzymes than the wheat isoamylases of the instant invention. There is simply no way that the potato starch synthases of Kossman *et al.* can have “the function of a wheat isoamylase”, as recited in the claims of the present application. Starch synthases catalyze a polymerization reaction, whereby a glucosyl residue of ADP-glucose is transferred to an α -1,4-glucan. Conversely, the enzymes of the present invention break down branchings of glycogen and amylopectin, as is taught in the paragraph bridging pages 2 and 3 of the application, refuting the contention in the Office Action that there is a “lack of definition for a wheat isoamylase”. Furthermore, even if, as the Office Action alleges, the enzymes of Kossman *et al.* would hybridize with one of the claimed molecules under the conditions formerly claimed, and it is not admitted that they would, they still do not meet the limitation of being “a protein with the function of a wheat isoamylase”, as required by the claims. Finally, the enzymes of Kossman *et al.* are not isolated from wheat, as is now recited in claim 24.

Reconsideration and withdrawal of the rejection under Section 102 are requested.

IV. THE REJECTIONS UNDER 35 U.S.C. §103 ARE OVERCOME

Claims 24-28, 31, 32 and 35-45 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Kossman *et al.* taken with Vasil *et al.* Claims 24-28, 31, 32 and 35-42 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Kossman *et al.* taken with Baltensperger *et al.* The rejections will be addressed collectively and are traversed.

For reasons discussed above, Kossman *et al.* do not teach or suggest the claimed nucleic acid molecules. The enzymes of Kossman *et al.* are starch synthases, not debranching enzymes, and are isolated from potato, not wheat.

Vasil *et al.* and Baltensperger *et al.* do nothing to remedy the deficiencies of Kossman *et al.* Vasil *et al.* relates to a method for transforming wheat, however, the combination of references involving the transformation of wheat with a nucleic acid encoding a completely different enzyme from the current invention, would not result in the invention. Similarly,

Baltensperger *et al.* claim a method for isolating starch from grain crops. In no way can Baltensperger *et al.* be combined with Kossmann *et al.* to arrive at the instant invention.

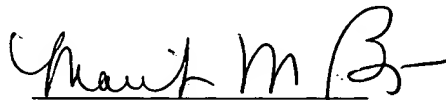
As the claimed invention is not taught or suggested by any of the cited references, alone or in combination, it cannot be obvious over them. Therefore, reconsideration and withdrawal of the rejections under Section 103 are requested.

CONCLUSION

Applicants believe that the application is in condition for allowance, and favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. Alternatively, consideration and entry of this paper is requested, as it places this application into better condition for purposes of appeal.

Respectfully submitted,

FROMMER LAWRENCE & HAUG LLP

By: 

Marilyn Matthes Brogan
Reg. No. 31,223

Anne-Marie C. Yvon, Ph.D.
Reg. No. 52,390
(212) 588-0800